72. (new) The assay of Claim 66 or 67, wherein the label is a radioisotope, an enzymatic label or a fluorescent label.

73. (new) The assay of Claim 68, wherein the label is a radioisotope, an enzymatic label or a fluorescent label.

74. (new) The assay of Claim 2, 57 or 58, wherein the test substance is a peptide, antibody, or small organic molecule.

REMARKS

Claims 1-17 and 46-56 were pending in the instant application. Applicants note that the Examiner has deemed the restriction requirement final and withdrawn Claims 9, 10, 46, 47, and 49-56 from consideration. In view of their withdrawal from consideration, Claims 9, 10, 46, 47, and 49-56 have been canceled, without prejudice to Applicant's right to pursue the non-elected subject matter of the canceled claims in related applications. Further, Claims 1, 13 and 48 have been canceled without prejudice to Applicants' right to pursue the subject matter of the canceled claims in related applications. Applicants have amended Claims 2, 4-8, 11, 12, 14 and 15 and added new Claims 57-74 to more particularly point out and distinctly claim the subject matter of the invention. The amendments and new claims are fully supported by the instant specification, *e.g.*, see page 18, line 19 to page 30, line 9, and do not represent new subject matter. A marked up version of the claims amended herein, with additions and deletions indicated by underlining and brackets, respectively, is attached hereto as Exhibit A. Claims 2-8, 11, 12, 14-17, and 57-74, therefore, will be pending upon entry of the instant amendment. A copy of the pending claims is attached hereto as Exhibit B.

Entry of the amendments and consideration of the remarks into the record of the instant application is respectfully requested.

1. THE OBJECTION TO THE CLAIMS SHOULD BE WITHDRAWN

Claims 1, 11, 15 and 48 are objected to because they fail to reflect the restriction requirement set forth in the last Office Action. Applicants have canceled Claim 1, without prejudice to Applicants' right to pursue the subject matter of the canceled claim in a related

application. Applicants have also amended Claims 11, 15 and 48 to reflect the restriction requirement. In view of the cancellation of Claim 1 and the amendments Claims 11, 15 and 48, the objection to the claims is moot. Accordingly, Applicants respectfully request that the objection be withdrawn.

2. THE REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

Claims 1-8 and 11-17 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner contends that the specification lacks written description support for the negative limitation that the substance of interest cannot be an antibody. For the reasons detailed below, Applicants assert that the rejection under 35 U.S.C. § 112, first paragraph, for lack of written description cannot stand and should be withdrawn.

In order to expedite the prosecution of this application, Applicants have canceled Claims 1 and 13, without prejudice and amended Claims 2, 4-8, 11, 12, 14 and 15. In particular, Claims 2, 11, 12, and 14 have been amended for reasons of clarity. Claims 4-8 and 15 have been amended to change their dependency. The cancellation of Claim 1 and the amendments to Claims 2, 4-8, 11, 12, 14 and 15 render the rejection under 35 U.S.C. § 112, first paragraph, for lack of written description moot. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, for lack of written description be withdrawn.

Claims 1-8, 11-17, and 48 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. In particular, the Examiner contends that the specification fails to provide sufficient support for the breadth of the claimed invention. The Examiner contends that the specification fails to provide sufficient guidance with respect to the molecular determinants modulating the specific binding interactions of the viral and cellular proteins, and thus, fails to provide sufficient guidance to enable the skilled artisan to predict which peptides of either the viral or cellular protein should be employed in the screening assay. The Examiner also contends that the specification fails to provide a sufficient number of working embodiments.

For all the reasons set forth below, Applicants assert that the rejections under 35 U.S.C. §112, first paragraph, for lack of enablement should be withdrawn.

The test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation from the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed. *U.S. v. Telectronics, Inc.* 857 F. 2d 778, 8 U.S.P.Q. 2d 1217 (Fed. Cir. 1988). Enablement is not precluded even if some experimentation is necessary. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F. 2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). The Court of Appeals for the Federal Circuit has determined that experimentation, though laborious, is not undue experimentation where the specification provides a reasonable amount of guidance. *In re Wands*, 858 F. 2d 731 (Fed. Cir. 1988). In the present instance, the specification provides one of ordinary skill in the art with sufficient guidance to meet the requirements of Section 112.

Further, while the predictability of the art can be considered in determining whether an amount of experimentation is undue, mere unpredictability of the result of an experiment is not a consideration. Indeed, the Court of Custom and Patent Appeals in *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976), has explicitly cautioned that the unpredictability of the result of an experiment is not a basis to conclude that the amount of experimentation is undue:

> If ... the disclosure must provide guidance which will enable one skilled in the art to determine, with reasonable certainty before performing the reaction, whether the claimed product will be obtained, then all experimentation is undue, since the term experimentation implies that success of the particular activity is uncertain. Such a proposition is contrary to the basic policy of the Patent Act ... 190 USPQ at 219.

Applicants respectfully assert that the specification coupled with information known as of the effective filing date of the instant application provides sufficient guidance to enable one of skill in the art to practice the claimed invention (*i.e.*, assays for the identification of substances that inhibit the interaction between influenza virus nucleoprotein and a host cell protein) without undue experimentation.

First, contrary the Examiner's contention, the specification does, indeed, describe a sufficient number of host cell proteins that interact with influenza virus nucleoprotein. In

particular, the specification describes six host cell proteins, nucleoprotein interactor ("NPI")-1, NPI-2, NPI-3, NPI-4, NPI-5, and NPI-6, that interact with influenza virus nucleoprotein. As indicated in Table I of the specification, NPI-1 through NPI-6 are distinct host cell proteins that interact with influenza virus nucleoprotein. The specification also provides sufficient guidance to enable one of skill in the art to identify other host cell proteins that interact with influenza virus nucleoprotein which can be employed in the assays of the claimed invention (see, *e.g.*, page 9, lines 11-29 of the specification). Further, Applicants submit that techniques for identifying host cell proteins that interact with influenza virus nucleoprotein were known to those of skill in the art as of the effective filing date of the instant application. Thus, the specification coupled with the information known as of the effective filing date of the instant application have would have enabled one of skill in the art to identify host cell proteins that interact with influenza virus nucleoprotein which could be employed in the assays of the claimed methods invention without undue experimentation.

Second, Applicants assert that the specification provides sufficient guidance regarding methods for the identification of peptide fragments comprising the binding domain of the respective protein for use in the methods of the claimed invention (see, *e.g.*, page 20, line 11 to page 21, line 3 of the specification). In fact, the specification describes a peptide fragment of the host cell protein NPI-1 comprising amino acid residues 262 to 527 that binds to influenza virus nucleoprotein. Moreover, standard techniques, such as, *e.g.*, mutagenesis, for identifying the binding site of a protein were known in the art as of the effective filing date of the instant application. Thus, Applicants assert that the specification coupled with the information known as of the effective filing date of the instant application would have enabled one of skill in the art to ascertain the amino acid residues of influenza virus nucleoprotein required for the interaction with a host cell protein as well as the amino acid residues of a host cell protein required for the interaction with influenza virus nucleoprotein without undue experimentation. Therefore, Applicants submit that one of skill in the art as of the effective filing date of the instant application would have been able to ascertain which peptide fragments of either the influenza virus nucleoprotein or a host cell protein to employ in the assays of the claimed invention without undue experimentation. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement be withdrawn.

In view the foregoing, Applicants submit that the pending claims have written description support in the specification and are fully enabled for the scope of the claimed subject matter. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

CONCLUSION

Applicants believe that the present claims meet all of the requirements for patentability. Entry and consideration of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Withdrawal of all the rejections and consideration of the pending claims is requested. An early allowance is earnestly sought.

If any issues remain, the Examiner is requested to telephone the undersigned at (212) 790-6431.

Respectfully submitted,

Date December 20, 2001

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Enclosures

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